

REMARKS

The foregoing amendments and the following remarks are responsive to the May 23, 2008 Office Action (the "Office Action").

Claim Rejections:

While Applicants respectfully disagree with the Examiner's rejections, to advance prosecution, Applicants have amended one or more claims to address the Examiner's comments. Applicants are not acquiescing to the rejections and reserve the right to pursue in a related application claims at least as broad as the amended claims prior to the amendments set forth herein. Applicants respectfully request the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Claim Rejections – 35 U.S.C. 102 – Claims 1, 2, 5, 9, and 10:

The Examiner rejected Claims 1, 2, 5, 9, and 10 under 35 U.S.C. 102(b) as being anticipated by International Application Publication No. WO 84/01904 ("Swanbeck"). Respectfully stated, none of Claims 1, 2, 5, 9, and 10 is anticipated by Swanbeck under 35 U.S.C. 102(b) because Swanbeck does not show every element of each claim arranged as in each claim, before or after the above amendments. See MPEP §2131. Moreover, as discussed below, Swanbeck also does not render any of these claims obvious.

Regarding Applicants' amended Claim 1, respectfully stated, Swanbeck does not disclose or suggest, inter alia, an apparatus for irrigating, supplying thermal energy to, and cleansing wounds, comprising a fluid flow path (comprising a conformable wound dressing, at least one inlet pipe communicating with at least a fluid reservoir, and at least one outlet pipe), a means for fluid cleansing in communication at least with the outlet pipe and the fluid reservoir, a fluid recirculation tube for directing cleansed fluid from the means for fluid cleansing back into the inlet pipe so that at least nutrients, molecules, factors, physiologically active components and/or other components from the wound dressing that aid in proliferation or that are favorable to the wound healing process are returned to the wound, a device for moving fluid through the wound dressing and a means for fluid cleansing, a means for supplying thermal energy to the fluid provided to the wound so as to maintain the wound at a temperature between 34 and 40 degrees

Celsius to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing, and a means for bleeding the flowpath, the apparatus being configured such that fluid can be supplied to fill the fluid flow path from the fluid reservoir and such that at least a portion of the fluid flowing through the outlet pipe can be recirculated via the fluid recirculation tube through the fluid flow path, as set forth in Claim 1.

Swanbeck at page 4, lines 3-5 states that "the treatment solution may be placed in thermostatically regulated water bath to ensure a certain temperature of the treatment solution." Swanbeck does not disclose or suggest that the thermostatically regulated water bath maintains the wound at a temperature between 34 and 40 degrees Celsius to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing, as set forth in Claim 1.

Nor does Swanbeck discuss, suggest, or contemplate any of the many physiological benefits of increasing the temperature of the wound that are discussed in Applicants' specification and that support Claim 1. As stated in paragraphs 25-27 of the Applicants' published patent application (U.S. Patent Application Publication No. US 2007/0129707 A1), "it is generally believed that the body's own metabolic activities are at an optimum at or near the temperature naturally occurring in the relevant bodily part. Examples of metabolic molecules involved in tissue healing processes that are beneficial in promoting wound healing include enzymes, growth factors and anti-inflammatories, and other physiologically active components of the exudate from a wound. These are believed to act best at temperatures found in the relevant bodily part and which they occur, varying between normal temperatures found at the body surface and those of the body core." Additionally, as stated in paragraph 28 of Applicant's Application Publication, "[w]ounds, and in particular chronic wounds, may have a lower temperature, e.g. 24 to 26° C., i.e. substantially below the optimum temperature. Thus, the temperature of the wound itself is deleterious to wound healing."

Although no such rejection is presently stated, Applicants respectfully submit that a rejection based on "optimum or workable ranges" based on Applicants' amended Claim 1 would be inappropriate where the prior art does not teach or suggest the desirability of the result achieved. As discussed in MPEP § 2144.05, "[a] particular parameter must first be recognized as a result-effective variable, i.e., a variable that achieves a recognized result, before the

determination of the optimum or workable ranges of said variable might be characterized as routine experimentation.” In re Antonie, 559 F.2d 618, 195 U.S.P.Q. 6 (CCPA 1977). Thus, for a rejection to be made based on optimum or workable ranges, the prior art must first identify the result which the variable achieves. Without Swanbeck teaching the desired results of maintaining the wound at a temperature between 34 and 40 degrees Celsius (e.g., to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing, as set forth in Claim 1), the temperature range recited in amended Claim 1 would not have been merely a matter of design choice.

Thus, Swanbeck does not disclose, suggest, or appreciate, inter alia, that the means for supplying thermal energy to the fluid of Applicants’ Claim 1 is configured so as to maintain the wound at a temperature between 34 and 40 degrees Celsius to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing.

Additionally, because the wound may be in a highly exuding state, this may cause a positive change in the balance of fluid in recirculation. As such, Claim 1 further provides a means for bleeding the fluid flow path to bleed fluid from the recirculation tube, in order to maintain the proper amount of fluid in the flow path and, hence, regulate the pressure within the flowpath. Swanbeck, by contrast, neither contemplates nor appreciates the desirability of the combination of features of Applicants’ Claim 1, and particularly fails to teach or suggest the use of a means for bleeding the fluid flow path as set forth in Claim 1. In particular, the apparatus illustrated in Swanbeck’s Figure 1 makes clear that all of the fluid removed from the suction cup (10) is routed to the bottle (15), without any of that fluid being removed by a bleeding means.

Regarding Claims 2, 5, 9, and 10, respectfully stated, these claims are not anticipated or suggested by Swanbeck for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions. Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the rejection of Claims 1, 2, 5, 9, and 10 in view of the amendments and clarifications listed above.

Claim Rejections – 35 U.S.C. 103 – Claims 6-8:

The Examiner rejected Claims 6-8 under 35 U.S.C. 103(a) as being unpatentable over Swanbeck in view of International Application Publication No. WO 00/50143 (“Burbank”).

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Respectfully stated, Claims 6-8 are not unpatentable over Swanbeck in view of Burbank because Burbank does not overcome Swanbeck's failure to disclose or suggest all of the limitations set forth in the claims from which Claims 6-8 depend (described above), and because the additional patentable limitations set forth in Claims 6-8 and the limitations of the claims from which they depend would not have been obvious to one of ordinary skill in the art in view of Swanbeck and Burbank at the time of the inventions.

New Claims Have Been Added:

New Claims 11-23 have been added. These claims are fully supported by the application as filed such that no new matter has been introduced by this Amendment. Regarding the art references cited in the Office Action, Applicants submit that Claims 11-23 are not anticipated or suggested by, or unpatentable over, the cited references for at least the same reasons as for Claims 1-10, and also because they each recite further patentable distinctions.

Double Patenting:

Claim 1 stands rejected on the ground of non-statutory obviousness type double patenting over Claim 1 of U.S. Patent Application No. 10/576,263. According to the Office Action, "a nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s)."

Applicants respectfully submit that Claim 1 of the present application *is* patentably distinct from Claim 1 of the '263 application because Claim 1 of the present application is not anticipated by or obvious in view of Claim 1 of the '263 application. In particular, Claim 1 of the present application recites a means for supplying thermal energy to the fluid provided to the wound, which limitation is not disclosed in Claim 1 of the '263 application or obvious in view of Claim 1 of the '263 application.

With respect to the Examiner's rejection based on 37 CFR 1.78(b) that Claim 1 conflicts with Claim 1 of the '263 application, Applicants respectfully disagree. As mentioned above, Claim 1 of the present application recites means for supplying thermal energy to the fluid

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provided to the wound so as to maintain the wound at a temperature between 34 and 40 degrees Celsius to optimize the metabolic activities of physiologically active components within the wound dressing and promote wound healing, which indicates a clear demarcation from the claimed subject matter of the '263 application. Further, in view of the amendments made to the claims as presented herein, Applicant submits that the claims are not conflicting.

For at least these reasons, Applicants respectfully submit that Claim 1 of the present application is patentably distinct from Claim 1 of the '263 application and respectfully request the Examiner to withdraw the obviousness-type double patenting rejection.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicants wish to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial Number | Title | Filed |
|----------------------------|--------------------------------------------------------------|-------|
| 60/989,723 SMNPH.001PR | SUCTION DEVICE AND DRESSING | |
| 10/533,275 SMNPH.002APC | APPARATUS FOR ASPIRATING, IRRIGATING AND CLEANSING WOUNDS | |
| 10/576263 SMNPH.003APC | WOUND CLEANSING APPARATUS WITH ACTIVES | |

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| 10/575871 SMNPH.005APC | WOUND CLEANSING APPARATUS IN-SITU | |
| 10/575870 SMNPH.006APC | WOUND CLEANSING APPARATUS WITH SCAFFOLD | |
| 10/599,720 SMNPH.007APC | WOUND CLEANSING APPARATUS WITH STRESS | |
| 11/957860 SMNPH.007C1 | WOUND CLEANSING APPARATUS WITH STRESS | |
| 10/599722 SMNPH.008APC | DRESSING AND APPARATUS FOR CLEANSING THE WOUNDS | |
| 10/599,725 SMNPH.009APC | APPARATUS FOR CLEANSING WOUNDS WITH MEANS FOR SUPPLY OF THERMAL ENERGY TO THE THERAPY FLUID | |
| 10/599728 SMNPH.010APC | APPARATUS FOR ASPIRATING, IRRIGATING AND/OR CLEANSING WOUNDS | |
| 11/577642 SMNPH.011APC | SIMULTANEOUS ASPIRATE & IRRIGATE & SCAFFOLD | |
| 12/094963 SMNPH.020APC | FIBROUS DRESSING | |

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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